UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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BARBARA TRUSS,
individually and on behalf of
all others similar situated,

Plaintiff,

Case No. 7:21-CV-09845-VLB-AEK

-v-

BAYER HEALTHCARE
PHARMACEUTICALS INC., a Delaware
Corporation; BAYER HEALTHCARE LLC, a
Delaware limited liability company; BEIERSDORF,
INC., a Delaware corporation; and BEIERSDORF
NORTH AMERICA, INC., a Delaware corporation,

Defendants.
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BAYER HEALTHCARE PHARMACEUTICALS INC., BAYER HEALTHCARE LLC, BEIERSDORF, INC., AND BEIERSDORF NORTH AMERICA, INC.'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS

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Dated: March 25, 2022

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Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer HealthCare LLC, Beiersdorf, Inc., and Beiersdorf North America, Inc. (collectively, the "Defendants") respectfully submit this Memorandum of Law in Support of their Motion to Dismiss the First Amended Class Action Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6), or, in the alternative, to dismiss under Rule 12(b)(1) for lack of standing as to any surviving claim seeking injunctive relief.

PRELIMINARY STATEMENT

Plaintiffs Natalia Golson, Jack Kilgore, and Gabriela Pettibone (the "California Plaintiffs") and Plaintiff Barbara Truss (collectively, the "Plaintiffs") challenge the label and formulation of Coppertone Water Babies (SPF 50) (the "Product"). *See* First Amended Class Action Complaint ("FAC" or "Complaint") (ECF No. 29) ¶ 1. Plaintiffs assert a variety of state law claims all premised on the notion that the Product label is misleading because the Product is formulated with octocrylene, a Food and Drug Administration ("FDA") approved sunscreen ingredient. *See* FDA, *Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use* (posted Sept. 24, 2021).[1] Despite FDA's classification of octocrylene as a permissible active sunscreen ingredient, Plaintiffs complain that the octocrylene in the Product degrades into benzophenone over time, FAC ¶ 2, and, in turn, the Product label—which says nothing about benzophenone—deceives a reasonable consumer into believing that the Product is benzophenone-free, *id.* ¶ 72; *see also id.* ¶ 47.

The Complaint should be dismissed in full because Plaintiffs' claims are preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"). Plaintiffs impermissibly attempt to use state law to impose new labeling requirements that are "different from or in addition to, or [ ] otherwise

[1] https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTCMonograph_M020-SunscreenDrugProductsforOTCHumanUse09242021.pdf.

not identical with" the requirements found in the FDCA and associated regulations. *See, e.g.*, *Critcher v. L'Oréal USA, Inc.*, 959 F.3d 31, 35–38 (2d Cir. 2020).

Even assuming that Plaintiffs' claims are not preempted, Plaintiffs fail to state a claim under state law for a variety of independent reasons. *First*, Plaintiffs' express warranty claims fail because, *inter alia*, Defendants did not make any express warranties about octocrylene or benzophenone (and Plaintiffs did not rely on any such warranties even if Defendants had), and Plaintiffs' implied warranty claims fail because Plaintiffs are not in privity with Defendants and do not allege that the Product failed to work as intended. Plaintiff Truss' express and implied warranty claims also fail for the independent reason that Plaintiff did not provide pre-suit notice. *See, e.g.*, *Colpitts v. Blue Diamond Growers*, 527 F. Supp. 3d 562, 590 (S.D.N.Y. 2021). *Second*, Plaintiffs' statutory consumer protection claims should be dismissed because the Complaint fails to allege that Defendants made any representation—let alone a misrepresentation—about benzophenone. Plaintiffs therefore necessarily base their New York General Business Law ("GBL") and California state law claims on Defendants' alleged *omissions* regarding octocrylene, but these efforts fail because Plaintiffs did not allege that Defendants knew the Products that Plaintiffs purchased either contained or degraded into benzophenone. Even assuming, *arguendo*, that they had, Plaintiff Truss fails to allege that Defendants *alone* knew octocrylene could contain trace amounts of benzophenone, further dooming her GBL claims. In any event, Plaintiff Truss cannot use GBL state law claims to enforce alleged violations of the FDCA. *Conboy v. AT&T Corp.*, 241 F.3d 242, 257 (2d Cir. 2001). *Third*, Plaintiffs' unjust enrichment claims fail because, *inter alia*, Plaintiffs alleged an express agreement.

Finally, and in the alternative, should this Court determine that any of Plaintiffs' claims may proceed, their injunctive relief requests must be dismissed under Rule 12(b)(1). Plaintiffs fail

to allege any threat of future imminent harm and therefore lack standing under Article III to seek injunctive relief. *See*, *e.g.*, *Berni v. Barilla S.P.A.*, 964 F.3d 141, 147 (2d Cir. 2020); *Suarez v. Cal. Nat. Living, Inc.*, No. 17-cv-9847 (VB), 2019 WL 1046662, at *4 (S.D.N.Y. March 5, 2019).

BACKGROUND

Plaintiffs' Claims. Plaintiffs allege that they purchased the Product in New York (Truss) or California (Goldson, Kilgore, Pettibone) in 2021. FAC ¶¶ 51, 56, 61, 66. The Product label, Plaintiffs allege, deceives consumers because it does not disclose that octocrylene in the Product allegedly either contains trace amounts of benzophenone at the time of purchase or degrades into benzophenone over time. *Id.* ¶ 31 ("When purchasing raw octocrylene . . . , benzophenone is a contaminant found in octocrylene and cannot be removed by its entirety when octocrylene is being processed.") (citations omitted); *id.* ¶47 ("[N]othing on the Product label insinuates, states, or warns that the Product contains benzophenone or that the octocrylene in the Product degrades over time and results in an accumulation of benzophenone."); *id.* ¶ 2 ("[T]he Product is formulated with the chemical octocrylene which over time degrades, resulting in an accumulation of benzophenone."); *id.* ¶ 72 ("Defendants engaged in fraudulent, unfair, deceptive, misleading, and/or unlawful conduct by *omitting* material facts about the Product's ingredients and the benzophenone contamination affecting the Product.") (emphasis added). This alleged deception, in Plaintiff Truss' view, violates New York GBL §§ 349 and 350. *Id.* ¶¶ 77-116. This alleged deception, in the California Plaintiffs' view, violates California CLRA §§ 1750, *et seq*, FAL §§ 17500, *et seq*, and UCL §§ 17200, *et seq.*. *Id.* ¶¶ 117-154. Based on the same theory, Plaintiffs allege breach of express and implied warranty and unjust enrichment. *Id.* ¶¶ 155-176.

FDA's Monograph Comprehensively Regulates Sunscreen Labels and Approves Octocrylene Up To 10%. Through a variety of tools—including governing statutes, regulations, final rules, and enforcement policies—FDA comprehensively regulates over-the-counter ("OTC")

drugs. *See* 21 U.S.C. § 393. One of these tools is the monograph: "a kind of 'recipe book' covering acceptable ingredients, doses, formulations, and labeling." FDA, *Drug Applications for Over-the-Counter (OTC) Drugs* (March 31, 2020).[2] As the Second Circuit explained, the monograph is "a detailed regulation . . . for each therapeutic class of OCT drug products," which "allows manufacturers to bypass individualized review" of individual products they seek to market. *Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 710 F.3d 71, 75 (2d Cir. 2013). The OTC drug monographs provide comprehensive guardrails for "the safety, effectiveness, and labeling of all marketing OTC active ingredients." FDA, *Drug Applications for Over-the-Counter (OTC) Drugs* (March 31, 2020).[3] Through the monograph, FDA thoroughly regulates all facets of sunscreens, including labeling, ingredient formulation, and product testing.

For decades, FDA has established labeling and testing regulations for sunscreens, including through the monograph.[4] Over the past three years, FDA has actively regulated sunscreens, and Congress has specifically legislated in this area by enacting § 505G of the FDCA through the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"). *See* CARES Act § 3854, Pub. L. No. 116–136, 134 Stat. 281 (2020). The CARES Act set aside a 2019 proposed rule[5] and

[2] https://www.fda.gov/drugs/types-applications/drug-applications-over-counter-otc-drugs. Defendants cite and provide links to publicly-available FDA guidance and articles throughout this Motion. These documents are noticeable and therefore appropriately considered on a motion to dismiss. *See, e.g.*, *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 59–60 (2d Cir. 2016) ("Although this case partially arises on a motion to dismiss, we may properly take judicial notice of [FDA Guidance] (without converting Acorda's motion to dismiss into a motion for summary judgment) because the Guidance is publicly available and its accuracy cannot reasonably be questioned.") (citing Fed. R. Evid. 201(b)).

[3] https://www.fda.gov/drugs/types-applications/drug-applications-over-counter-otc-drugs.

[4] *See, e.g.*, 21 C.F.R. § 352 (1999) (the final sunscreen monograph of 1999 that included conditions for active ingredients to be generally recognized as safe and effective and was stayed indefinitely in 2001); 21 C.F.R. § 201.327 (2011) (the 2011 final sunscreen rule, which regulates the entirety of sunscreen product labels, with requirements applicable to products' principal display panels, uses, warnings, and directions); *see also* Guidance for Industry (May 2018) at 6, https://collections.nlm.nih.gov/master/borndig/101734210/UCM259001.pdf.

[5] At the time Congress enacted the Cares Act, an FDA proposed rule to amend the 1999 sunscreen monograph, which included suggested changes to sunscreen active ingredients, maximum sun protection factor (SPF) levels, broad spectrum requirements, dosage forms, labeling, and final formulation testing, was not yet final. *See* 84 Fed. Reg. 6204 (Feb. 26, 2019).

instead deemed final a sunscreen monograph adopting the requirements of the 1999 monograph (found in 21 C.F.R. § 352) plus the effectiveness and labeling requirements of the 2011 final rule (found in 21 C.F.R. § 201.327). *See* FDA, *Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use* (posted Sept. 24, 2021) (the "2020 Monograph").[6]

The 2020 Monograph—effective on March 27, 2020 under the CARES Act—provides the current binding requirements for sunscreen manufacturers. It expressly permits, for example, the formulation of sunscreen products using a combination of 16 sunscreen active ingredients below certain thresholds. *Id.* at 2–5. Critical here, one of these permissible ingredients is "Octocrylene up to 10%." *Id.* The 2020 Monograph also comprehensively regulates product labels. These regulations include requirements that the label contain effectiveness and water resistance claims, provide the established name of the drug, identify the product as a sunscreen, describe product uses, specify applicable warnings, provide product directions, and eliminate any false or misleading claims like "sunblock," "sweatproof," "waterproof," or "similar claims." *Id.* at 6–8. The 2020 Monograph also provides specific formulation and testing guidelines, as well as requirements for the frequency of testing and the number of subjects. *Id.* at 8–20. The CARES Act specifies that sunscreens manufactured and marketed within the boundaries set by the 2020 Monograph and other federal regulations are deemed to be generally recognized as safe and effective (or "GRASE"). *See* 2020 Monograph at 1.[7]

[6]https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTCMonograph_M020-SunscreenDrugProductsforOTCHumanUse09242021.pdf.
[7] *See also supra,* n.1.

ARGUMENT

A complaint must be dismissed under Rule 12(b)(6) if it does not "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "[L]abels and conclusions" or "formulaic recitation of the elements of a cause of action" do not suffice. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

Because a preemption defense is grounded in law, it is properly raised on a motion to dismiss and properly decided absent a full factual record. *See Critcher*, 959 F.3d at 38 (dismissing complaint on preemption grounds). Dismissal is appropriate "if the statute's barrier to suit is evident from the face of the complaint." *Ricci v. Teamsters Union Local 456*, 781 F.3d 25, 28 (2d Cir. 2015).

I. THE FDCA PREEMPTS PLAINTIFFS' CLAIMS BECAUSE THEY ALL SEEK TO IMPOSE REQUIREMENTS REGARDING BENZOPHENONE DIFFERENT FROM OR IN ADDITION TO THOSE UNDER FEDERAL LAW.

Plaintiffs' claims are expressly preempted because they seek to impose requirements different from or in addition to requirements imposed pursuant to the FDCA. The Second Circuit recently held in *Critcher* that the FDCA preempted virtually identical claims. 959 F.3d at 31.[8] *Critcher* governs, and Plaintiffs' First Amended Complaint must be dismissed.

Congress has prohibited states from establishing any requirement relating to the regulation of an OTC drug "different from or in addition to, or that is otherwise not identical with" a requirement under the FDCA. 21 U.S.C. § 379r(a)(2); *see Critcher*, 959 F.3d at 35 (recognizing Congress added "an expansive preemption provision" to the FDCA). In practice, this provision

[8] *Critcher* applied the FDCA's preemption provision for cosmetic products. That provision is substantively identical to the neighboring preemption provision for OTC drugs with one notable exception: the drug preemption provision is broader. The cosmetics provision limits the ban to requirements for "labeling or packaging," but the drug preemption provision prohibits the imposition of *any* state law requirements—whether they relate to labeling, packaging, or any other element of the product at issue. *See Bimont v. Unilever U.S., Inc.*, No. 14-cv-7749 (JPO), 2015 WL 5256988, at *2 (S.D.N.Y. Sept. 9, 2015) (discussing the "[s]imilar language" of the two preemption provisions).

means the FDCA preempts both state laws that conflict with the FDCA *and* state laws that provide "requirements that are not *exactly the same* as those set forth in the FDCA and its regulations (*i.e.*, any law that is 'in addition to' the FDCA)." *Critcher*, 959 F.3d at 35–36 (emphasis in original) (reasoning that claims requiring the manufacturer to "make an additional disclosure on its packaging" beyond those "already mandated in the FDCA and the regulations promulgated thereunder" are preempted by the FDCA).

Plaintiffs do not allege the Product fails to comply with any requirement in the 2020 Monograph. Instead, Plaintiffs essentially seek to use state law to *add* to the 2020 Monograph's requirements, *contra Critcher*, 959 F.3d at 35–36, using their respective claims to achieve one of the following: a reformulation of the Product without octocrylene, or a new label warning that octocrylene may potentially degrade into benzophenone over time. But Plaintiffs ignore that octocrylene is on the 2020 Monograph's list of permissible active ingredients. *See* FAC ¶ 26 (label identifying that the Product contains 9% of octocrylene); 2020 Monograph at 2–3 (permitting the use of octocrylene up to 10%).[9] Plaintiffs' contention that state law mandates reformulation without octocrylene thus would impose state law requirements in addition to and in conflict with those in the 2020 Monograph, which expressly contemplates formulation *with* octocrylene.

[9] Consistent with the CARES Act, FDA issued a proposed order in September 2021 seeking additional data on some of these ingredients, including octocrylene. *See* CARES Act §§ 3851(a)(2), 3854(c)(1)(B); FDA, *Proposed Order: Amending Over-the-Counter (OTC) Monograph M020: Sunscreen Drug Products for OTC Human Use* (issued Sept. 24, 2021) ("2021 Proposed Order"). In issuing the 2021 Proposed Order, however, FDA emphasized that the "proposed order does not represent a conclusion by FDA that . . . [the ingredients] proposed here as needing additional data, are unsafe for use in sunscreens. Rather, we are requesting additional information on these ingredients so that we can evaluate their GRASE status in light of changed conditions." *Id.* at 5. FDA additionally specified that "[t]he deemed final order, which came into existence by operation of law on March 27, 2020 through the enactment of the CARES Act, established the current monograph for OTC sunscreen products." FDA, *Questions and Answers: FDA Posts Deemed Final Order And Proposed Order For Over-The-Counter Sunscreen* (Nov. 16, 2021) (https://www.fda.gov/drugs/understanding-over-counter-medicines/questions-and-answers-fda-posts-deemed-final-order-and-proposed-order-over-counter-sunscreen). In other words, the 2021 Proposed Order is just that—a proposal.

Plaintiffs' request for a new label warning is likewise doomed under *Critcher*. *See* 959 F.3d at 35. Plaintiffs complain that "nothing on the Product label insinuates, states, or warns that the Product contains benzophenone or that the octocrylene in the Product degrades over time and results in an accumulation of benzophenone." FAC ¶ 47. But there is no question that the Product complies with the labeling requirements found in the 2020 Monograph. Indeed, as required by the Monograph, the principal display panel of the Product provides that it is "Water Resistant (80 Minutes)" and provides "Broad Spectrum SPF 50." FAC ¶ 49; 2020 Monograph at 3–4. The label identifies the Product as a sunscreen lotion, warns against use on damaged or broken skin, informs the consumer to keep the Product out of their eyes and stop use in the event of a rash, provides directions, and does not contain any of the false or misleading claims identified (or even similar to those identified) in the Monograph. FAC ¶ 26; 2020 Monograph at 4–6; *id.* at 1 ("An over-the-counter (OTC) sunscreen drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this OTC monograph and each general condition established in 21 C.F.R 330.1."). An octocrylene or benzophenone warning would *add* to the long list of labeling requirements FDA saw fit to include in the 2020 Monograph, and any claim seeking such an additional warning is plainly preempted under *Critcher*. *See* 959 F.3d at 35–36; *see also Young v. L'Oréal*, No. 21-cv-0446 (GHW) (KHP), 2021 WL 2295625, at *5 (S.D.N.Y. May 20, 2021), *report and recommendation adopted*, 2021 WL 2292341 (S.D.N.Y. June 4, 2021).

In short, through their Complaint, Plaintiffs seek to accomplish exactly what Congress sought to prevent in passing section 379r of the FDCA. As the Second Circuit has explained,

> Congress or the FDA could have chosen to mandate such additional labeling when they established the comprehensive regulatory regime governing [food, drugs, and] cosmetics, but they did not. And because of the broad preemption provision that Congress *did* choose

> to include, Plaintiffs cannot now seek to impose those requirements through alternative means grounded in state law.

Critcher, 959 F.3d at 36–37; *see also Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 376 (S.D.N.Y. 2014). The Court should dismiss the FAC because all claims therein are preempted by federal law. 21 U.S.C. § 379r(a)(2).

II. EVEN IF THE FDCA DID NOT PREEMPT PLAINTIFFS' STATE LAW CLAIMS, PLAINTIFFS FAIL TO STATE A CLAIM UNDER STATE LAW.

A. Plaintiffs' Breach of Warranty Claims Fail.

Plaintiffs' breach of warranty claims cannot survive. The express warranty claims fail because Defendants made no warranties whatsoever about octocrylene or benzophenone, and Plaintiffs failed to plead that they relied on any alleged warranties. The implied warranty claims also fail, because Plaintiffs and Defendants are not in privity and the Products are fit for their intended purpose—as sunscreen. Plaintiff Truss' warranty claims additionally fail because she did not provide pre-suit notice.

1. Plaintiffs' Express Warranty Claims Fail Because Defendants Did Not Make Any Warranties Regarding Octocrylene Or Benzophenone and Plaintiffs Did Not Rely On Any Such Warranties, And Plaintiff Truss' Claim Fails For Lack Of Pre-Suit Notice.

Plaintiffs' claims for breach of express warranty fail because Defendants have neither made an express warranty nor breached it. Under New York and California law, breach of express warranty requires Plaintiffs to prove "(1) the existence of a material statement amounting to a warranty, (2) the buyer's reliance on this warranty as a basis for the contract with the immediate seller, (3) breach of the warranty, and (4) injury to the buyer caused by the breach." *Colpitts*, 527 F. Supp. 3d at 589; *Sanders v. Apple Inc.*, 672 F. Supp. 2d 978, 987 (N.D. Cal. 2009) (same).

First, Plaintiffs allege that Defendants created "an express warranty that the Product is safe for its intended use," FAC ¶ 159, but there is no such *express* written statement on the Product

label. *See, e.g.*, *Harris v. Pfizer Inc.*, No. 21-cv-6789 (DLC), 2022 WL 488410, at *7 (S.D.N.Y. Feb. 16, 2022) (dismissing express warranty claim for failure to allege that Pfizer "issued any express warranty that their medication was completely safe or free from" contaminant at issue). In fact, Defendants made no warranties whatsoever about octocrylene or benzophenone. Rather, Plaintiffs essentially ask this Court to infer that all sunscreens with octocrylene—an ingredient expressly permitted by the 2020 Monograph—are unsafe for their intended use. Not only is it illogical to conclude that FDA-approved active ingredients are inherently unsafe, but such attempts to infer express warranties out of thin air are consistently rejected. *See*, *e.g.*, *Harris*, 2020 WL 488410, at *7.[10] This Court should follow suit.

Second, even if Plaintiffs had identified an express warranty about benzophenone, they failed to plead any reliance on such a warranty. *See, e.g.*, *Oden v. Bos. Sci. Corp.*, 330 F. Supp. 3d 877, 895 (E.D.N.Y. 2018) (dismissing express warranty claim where plaintiffs alleged reliance on promotional statements but "the Complaint [wa]s devoid of any facts that would permit the inference that Plaintiff actually read these statements and directly relied upon them when making the decision to utilize Defendant's product"); *Sanders*, 672 F. Supp. 2d at 988 (dismissing express warranty claim for failure "to allege reasonable reliance on any specific representations"); *Asghari v. Volkswagen Grp. of Am., Inc.*, 42 F. Supp. 3d 1306, 1335 (C.D. Cal. 2013) (same).

Finally, Plaintiff Truss' express warranty claim fails because she has not provided pre-suit notice of the alleged breach. Under New York law, "a plaintiff must also give notice of the breach to the seller before he can recover under an express warranty claim." *Colpitts*, 527 F. Supp. 3d at

[10] *Accord Sarr v. BEF Foods Inc.*, No. 18-cv-6409(ARR), 2020 WL 729883, at *7 (E.D.N.Y. Feb. 13, 2020) (dismissing express warranty claim because the defendant "did not expressly warrant that the Mashed Potatoes did not contain vegetable oil"); *Twohig v. Shop-Rite Supermarkets, Inc.*, 519 F. Supp. 3d 154, 167 (S.D.N.Y. 2021) (similar); *Becerra v. Dr Pepper/Seven Up, Inc.*, No. 17-cv-05921-WHO, 2018 WL 3995832, at *9 (N.D. Cal. Aug. 21, 2018) (dismissing express warranty claim for failure to allege that the term "diet" warranted that consumers would lose weight), *aff'd*, 945 F.3d 1225 (9th Cir. 2019).

589; *see* N.Y. U.C.C. § 2-607(3)(a) ("[B]uyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach."). Plaintiff did not and cannot plead that she provided pre-suit notice to Defendants, and this "failure to satisfy the pre-suit notice requirement is fatal to [her] breach of express warranty claim[.]" *Colpitts*, 527 F. Supp. 3d at 590.

2. Plaintiffs' Implied Warranty Claims Fail For Lack of Privity And Because The Product Is Fit For Its Intended Purchase, And Plaintiff Truss' Implied Warranty Claims Fails For Lack Of Notice.

First, Plaintiffs' implied warranty claims fail because Plaintiffs lack privity with Defendants. *See Colpitts*, 527 F. Supp. 3d at 591 (dismissing New York implied warranty claims with prejudice for lack of privity); *Clemens*, 534 F.3d at 1023 (affirming dismissal of California implied warranty claim due to a "lack of vertical privity"). The Complaint confirms that no privity existed between Plaintiffs and Defendants because each Plaintiff purchased the Product from third-party retailers (*i.e.*, Walgreens, Rite-Aid, Walmart). FAC ¶¶ 51, 56, 61, 66. "This lack of an immediate transaction 'renders [P]laintiff a remote purchaser who is barred as a matter of law from claiming economic damages due to [Defendant's] alleged breach of implied warrant[y].'" *Colpitts*, 527 F. Supp. 3d at 591.

Second, to state a claim for breach of implied warranty, Plaintiffs must plead the seller breached its "guarantee . . . that its goods are fit for the intended purpose for which they are used." *Colpitts*, 527 F. Supp. 3d at 590; *Viggiano v. Hansen Natural Corp.*, 944 F. Supp. 2d 877, 895-96 (C.D. Cal. 2013) (plaintiff failed to allege any facts suggesting that diet soda was not merchantable as a diet drink). In *Harris*, the district court rejected plaintiffs' allegation that a drug was unmerchantable for failure to show how the presence of contaminants rendered it "unfit for its ordinary purpose." 2022 WL 488410, at *8. Here too, Plaintiffs did not allege—indeed, because they cannot—that any amount of benzophenone rendered their Product unfit for the precise

purpose for which it was intended: an effective *sunscreen*. Plaintiffs' implied warranty claim therefore cannot survive.

Finally, as with Plaintiff Truss' breach of express warranty claim, her claim for breach of implied warranty must also fail for lack of pre-suit notice. *Colpitts*, 527 F. Supp. 3d at 589 (the notice requirement also applies to claims for breach of implied warranty under New York Law); *see supra* II.A.1.

B. Plaintiffs' Statutory State Law Claims Fail Because, *Inter Alia*, They Do Not Allege A Misrepresentation Or Plead A Misrepresentation By Omission.

Each of Plaintiffs' statutory consumer claims should be dismissed because, although Plaintiffs generically complain of misrepresentations, they fail to identify a single affirmative misleading or deceptive statement about the Product. Plaintiffs also fail to allege any actionable omissions theory because they have not plausibly alleged that Defendants knew the Product contained or degraded into benzophenone before Plaintiffs purchased the Product—and Defendants' knowledge is necessary to establish an omissions claim under each statutory consumer claim.[11] Even assuming Plaintiffs did plead the requisite knowledge—which they did not—Plaintiff Truss fails to allege that Defendants *alone* knew octocrylene has the alleged potential to contain or degrade into benzophenone, and Truss' claim further fails because Second Circuit precedent forbids plaintiffs from attempting to leverage an alleged violation of statutes lacking private rights of action into a GBL claim.

[11] Even if an affirmative statement or actionable omission existed, the Court should still dismiss statutory claims brought by the California Plaintiffs under the UCL, CLRA, and FAL. Under those statutes, a plaintiff must allege sufficient facts to show that he or she actually relied on the particular statements that he or she is challenging. *See Reid v. Johnson & Johnson*, 780 F.3d 952, 958 (9th Cir. 2015). To meet this burden, Plaintiffs must plead that the misrepresentation was "material" to them, i.e., "that without the misrepresentation, plaintiff[s] would not have acted as [they] did." *Cattie v. Wal-Mart Stores, Inc*., 504 F. Supp. 2d 939, 946 (S.D. Cal. 2007) (citing *Caro v. Procter & Gamble Co.*, 18 Cal. App. 4th 644, 668 (1993)). Plaintiffs have not met that standard. They simply make a conclusory claim that they "reasonably relied on Defendants' representations" when purchasing the Product. FAC ¶ 50. Without a plausible allegation of reliance, this Court must dismiss the California Plaintiffs' UCL, CLRA, and FAL claims. *See Iqbal*, 556 U.S. at 663–64.

1. Plaintiffs Fail To Allege A Misrepresentation.

Plaintiffs generically claim that "Defendants' representations were misleading to Plaintiffs and consumers because the Product contains benzophenone." FAC ¶ 50. But Plaintiffs do not and cannot identify any statement on the Product's labels (or by Defendants anywhere else) regarding the alleged relationship between octocrylene and benzophenone in the Product. And Courts repeatedly have recognized—including Judge Cote very recently—that the presence of a contaminant not listed on a drug's label is not a misrepresentation. *Harris*, 2022 WL 488410, at *7 (absent an express statement to the contrary, "[i]t is not enough to allege that the plaintiffs inferred from this label that the product did not contain" contaminants); *see*, *e.g.*, *Zottola v. Eisai Inc.*, 20-cv-02600 (PMH), 2021 WL 4460563, at *5 (S.D.N.Y. Sept. 29, 2021) (dismissing GBL claims because plaintiff "only refer[red] to unspecified misleading representations contained in the Medications' 'labels and disclosures'" regarding safety "as opposed to challenging a particular representation"); *Womack v. Evol. Nutrition Assocs.*, No. 6:21-cv-00332, 2021 WL 5906340, at *10 n.8 (N.D.N.Y. Dec. 14, 2021) (similar).[12]

At most, Plaintiffs point to the "hypoallergenic & gentle" phrase on the Product's label. FAC ¶ 49. This statement, however, does not relate at all to octocrylene or benzophenone. What is more, Plaintiffs failed to allege facts suggesting that the mere presence of octocrylene or benzophenone in the Product prevents it from being gentle or hypoallergenic. At least one court has held that a reasonable consumer would not expand the meaning of "hypoallergenic" beyond

[12] Additionally, Plaintiffs' claims brought under the UCL, FAL, and CLRA must comply with Rule 9(b)'s particularity requirements. *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009). The Second Circuit "has read Rule 9(b) to require that a complaint (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Rombach v. Chang*, 355 F.3d 164, 170 (2nd Cir. 2004) (citing *Mills v. Polar Molecular Corp.,* 12 F.3d 1170, 1175 (2d Cir.1993). The California Plaintiffs' UCL, CLRA, and FAL allegations do not meet this standard and should be dismissed for this reason alone.

its dictionary definition and conclude that the product is therefore free of potential contaminants. *See Rugg*, 2018 WL 3023493 at *3. Furthermore, this Court's dismissal decision in *Jones v. Orgain* is also instructive. No. 20-cv-8463 (VB), 2021 WL 4392783 (S.D.N.Y. Sept. 24, 2021). In *Jones,* plaintiff sued the manufacturer of a "Clean Protein, Grass Fed Protein Shake, Vanilla Bean Flavor," alleging the product was deceptively labeled in violation of §§ 349 and 350 because the product contained processed, synthetic, or artificial ingredients. *Id.* at *1. This Court rejected the argument, reasoning that "Plaintiff fail[ed] plausibly to allege the product packaging made any statement or representation that it contained no processed, synthetic, or artificial ingredients." *Id*. at *3. Similarly here, "hypoallergenic & gentle" does not convey that octocrylene—an ingredient plainly sanctioned by the 2020 Monograph—is free of traces of other components. Nowhere on the labeling do Defendants make any representation that the Product is free from benzophenone, and a reasonable consumer would not read the words "hypoallergenic and gentle" and assume the Product is benzophenone-free. *See*, *e.g.*, *Harris*, 2022 WL 488410, at *7 ("It is not enough to allege that the plaintiffs inferred from this label that the product did not contain N-nitroso-varenicline. A plaintiff does not have a claim under the GBL just because she comes away from an advertisement with an incorrect impression. That impression must be reasonably traceable to a misleading statement from the defendant."); *Sarr*, 2020 WL 729883, at *5; *Red v. Kraft Foods, Inc.*, No. cv-10-1028, 2012 WL 5504011, at *3 (C.D. Cal. Oct. 25, 2012) (Plaintiffs cannot pretend that a reasonable consumer "will read [the] true statement on [the] package," and then subsequently

disregard common sense and "assume things about the products other than what the statement actually says."). [13]

2. Plaintiffs Fail To Allege that Defendants Knew The Products Contained Benzophenone Before Plaintiffs Purchased The Products.

Because they have no basis for claiming misrepresentations, Plaintiffs' statutory claims are, in truth, about alleged omissions. FAC ¶ 112 ("Defendants engaged in misleading and deceptive advertising that *failed to disclose* that the Product contains benzophenone.") (emphasis added). But their omissions theory—that the absence of a warning about benzophenone constitutes deception and falsity—also fails as a matter of state law. [14] New York and California law require Plaintiffs to plead that Defendants knew the Products that Plaintiffs purchased contained benzophenone or degraded into benzophenone. Plaintiffs fail to do so.

Again, just weeks ago, Judge Cote dismissed an indistinguishable GBL claim predicated on an omissions theory because the plaintiffs did not plead that the manufacturer "knew about any . . . contamination in the medication that the plaintiffs purchased at the time they purchased it." *Harris*, 2022 WL 488410, at *7 (noting that plaintiff did "not plausibly allege that Pfizer knew about the nitrosamine contamination before it issued its recall"); *In re Sling Media Slingbox Advert. Litig.*, 202 F. Supp. 3d 352, 359 (S.D.N.Y. 2016) (Plaintiffs have failed to plead facts sufficient to show that Defendant had knowledge of the alleged omission, and therefore engaged in a deceptive or misleading act); *see, e.g.*, *Wilson v. Hewlett-Packard Co.*, 668 F.3d 1136, 1145

[13] In addition to the reasons stated, *supra* II.A and *infra* II.D, Plaintiffs' warranty claims and unjust enrichment claims also fail because there has been no misrepresentation or deception. *Jones v. Orgain*, 2021 WL 4392783, at *4; *see also Becerra*, 2018 WL 3995832, at *9 (express and implied warranty), *aff'd*, 945 F.3d 1225; *Robinson v. Wells Fargo Home Mortg.*, No. 16-cv-01619, 2016 WL 6524403, at *6 (N.D. Cal. Nov. 3, 2016) (unjust enrichment).

[14] Each Plaintiff's argument that Defendants' "omission" regarding alleged benzophenone in octocrylene—an ingredient expressly permitted by the 2020 Monograph—underscores again why Plaintiffs' claims are preempted. Plaintiffs are flatly asking for state law to impose a labeling requirement different from or in addition to, or that is not otherwise identical with FDA regulations, and their claims are therefore inappropriate. *See supra* Section I; *see also Rugg v. Johnson & Johnson*, No. 17-CV-05010 (BLF), 2018 WL 3023493, at *5 (N.D. Cal. June 18, 2018) (dismissing all claims based on omissions in labeling as preempted by the FDCA).

(9th Cir. 2012) ("[U]nder the CLRA, plaintiffs must sufficiently allege that a defendant was aware of a defect at the time of sale to survive a motion to dismiss.").

As in *Harris*, Plaintiffs fail to plead any facts that Defendants knew their Products contained or degraded into benzophenone before their purchases, beyond citations to studies about the potential relationship between octocrylene and benzophenone and a generalized allegation that the "personal care product industry has known for some time that octocrylene is contaminated with benzophenone." FAC ¶¶ 30–31. Ultimately, Plaintiffs have not alleged that Defendants had knowledge of relevant facts that they allegedly withheld from Plaintiffs regarding the Product.

3. Plaintiff Truss Fails To Allege That Defendants Alone Knew The Product May Contain Or Degrade Into Benzophenone.

Even if Plaintiffs alleged that Defendants knew their Products contained benzophenone or degraded into benzophenone, Plaintiff Truss pleads nothing to suggest that Defendants *alone* possessed information that octocrylene could potentially contain or degrade into benzophenone. In New York, "[i]n cases alleging a deceptive act based on an omission, it is not sufficient for a plaintiff to point solely to the omission," *Dimond v. Darden Rests., Inc.*, No. 13-cv-5244 (KPF), 2014 WL 3377105, at *13 (S.D.N.Y. July 9, 2014), because "the [GBL] surely does not require businesses to ascertain consumers' individual needs and guarantee that each consumer has all relevant information specific to its situation. The scenario is quite different, however, where the *business alone* possesses material information that is relevant to the consumer and *fails to provide this information*." *Oswego v. Laborers' Local 214 Pension Fund v. Marine Midland Bank, N.A.*, 647 N.E.2d 741, 745 (N.Y. 1995) (emphases added); *see also Beth Israel Med. Ctr. v. Verizon Bus. Network Servs., Inc.*, No. 11-cv-4509 (RJS), 2013 WL 1385210, at *8 (S.D.N.Y. Mar. 18, 2013) (citation omitted).

Plaintiff Truss does not allege that Defendants "alone" knew about the alleged relationship between octocrylene and benzophenone. In fact, her own allegations establish quite the opposite: she cites several publicly available websites in the Complaint that discuss the alleged potential for octocrylene to contain traces of benzophenone or degrade into benzophenone over time, including websites from other personal care product manufacturers. *See* FAC ¶¶30–38 (citing to the California Proposition 65 website, studies available online, and FAQs on the Rodan + Fields website regarding the alleged relationship between benzophenone and octocrylene). These allegations are fundamentally inconsistent with any ability to show that Defendants *alone* knew the alleged potential for octocrylene to contain trace amounts of benzophenone or degrade into benzophenone more generally. *See, e.g.*, *Dimond*, 2014 WL 3377105, at *13 (dismissing where plaintiff failed to plead facts to show that the omitted information was known to the business alone and could not be reasonably obtained by others).

4. Second Circuit Law Precludes Plaintiff Truss From Predicating Deception On The Alleged Violation Of Another Statute.

Additionally, Plaintiff Truss' claims fail for the independent reason that allegations regarding perceived violations of the FDCA and New York Public Health Law, FAC ¶¶ 41–42, cannot form the basis for GBL claims of deception. The Second Circuit repeatedly has held that the alleged violation of another statute, especially one lacking a private right of action, is insufficient to state a claim under GBL § 349. *See Conboy*, 241 F.3d at 257–58 (rejecting plaintiff's attempt to effectively create a private right of action under a state statute by arguing that defendant "engaged in a 'deceptive act' within the meaning of [GBL] Section 349 by violating [the other state law]"); *Broder v. Cablevision Sys. Corp*., 418 F. 3d 187, 199–200 (2d Cir. 2005) (applying *Conboy*, and holding that § 349 cannot be used to "circumvent the lack of a private right of action for violation of a *federal* law," and reiterating that circuit law precludes claiming that deception

exists because another statute or regulation was violated, particularly one "that on its face does not address deceptive or misleading behavior").[15]

C. Plaintiffs' Unjust Enrichment Claim Fails.

Plaintiffs' claim for unjust enrichment fails for two independently sufficient reasons: Plaintiffs allege they are in a contractual relationship with Defendants and Plaintiffs' alleged basis for their claim is a purported statutory violation.

First, Plaintiffs' claim fails because it rests on quasi-contractual principles applicable only in the absence of an express contract governing the subject at issue. *See, e.g.*, *Paracor Fin., Inc. v. Gen. Elec. Cap. Corp*., 96 F.3d 1151, 1167 (9th Cir. 1996) ("[T]he existence of a valid and enforceable written contract … ordinarily precludes recovery in quasi-contract" under New York and California law.) (internal citations omitted); *MacDraw, Inc. v. The CIT Grp. Equip. Fin, Inc.*, 157 F.3d 956, 964 (2d Cir. 1998). But Plaintiffs hold themselves out as having "formed a contract with Defendants at the time Plaintiff and each member of the Classes purchased the Product," FAC ¶ 156, in order to support their breach of warranty claims. The alleged existence of a contract between the parties defeats Plaintiffs' quasi-contractual unjust enrichment claims on the same subject.

Second, Plaintiffs focus their unjust enrichment claim on purported violations of the FDCA, which they in turn seek to enforce through other statutory consumer protection claims and common law causes of action. As set forth below, Plaintiffs have not shown any of the violations on which their unjust enrichment claims rely, and thus there is no unjust conduct alleged. But even assuming that Plaintiffs could make such a showing, Plaintiffs may not support an unjust

[15] To the extent any of Plaintiffs' claims are based solely on alleged violations of the FDCA, *see* FAC ¶¶ 41–42, they all fail because state-law claims based only on violations of the FDCA preempt state law. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 & n. 4 (2001); *see also Verzani v. Costco Wholesale Corp.*, No. 09-cv-2117(CM), 2010 WL 3911499, at *3 (S.D.N.Y. Sept. 28, 2010) (dismissing claims predicated on FDCA violations).

enrichment claim by simply porting over the wrong from another cause of action. *See, e.g.*, *Harris*, 2022 WL 488410, at *9 (unjust enrichment claim "is not available where it simply duplicates, or replaces, a conventional contract or tort claim"); *In re Sony PS3 Other OS Litig.*, 551 F. App'x 916, 923 (9th Cir. Jan. 6, 2014) (affirming dismissal of unjust enrichment claim because "[i]n light of the adequate legal remedies available, Plaintiffs cannot state a claim for unjust enrichment").[16] Plaintiffs' unjust enrichment claims are duplicative of their warranty claims and other state law claims in that they are all based on the same alleged misrepresentation or omission on the Product's packaging. *See, e.g.*, FAC ¶ 175 ("Defendants' labeling of the Product was misleading to consumers, which caused injuries to Plaintiffs and the other members of the Classes because they would have not purchased the Product if Defendants had disclosed that the Product contained benzophenone."). Ultimately, Plaintiffs' unjust enrichment claim cannot stand.

III. EVEN IF PLAINTIFFS' CLAIMS SURVIVE DISMISSAL, PLAINTIFFS LACK STANDING TO SEEK INJUNCTIVE RELIEF.

Plaintiffs request injunctive relief regarding Defendants' labeling practices. *See, e.g.*, FAC ¶¶ 75, 87, 115, 127, 143, 153. Even if any Plaintiff stated a claim, these requests for injunctive relief must be dismissed for lack of Article III standing under Rule 12(b)(1). The Second Circuit has made clear that "to maintain an action for injunctive relief, a plaintiff 'cannot rely on past injury . . . but must show a likelihood that he . . . will be injured in the future.'" *Berni*, 964 F.3d at 147 (2d Cir. 2020) (explaining that any such future harm must be "imminent"). Plaintiffs plead no possibility of future harm, let alone imminent future harm. *See id.* ("For several reasons, past

[16] California Plaintiffs' UCL and FAL claims fail for the same reason. Under California law, remedies available under these statutes are "generally limited to . . . equitable remedies"—making them "'subject to fundamental equitable principles, including inadequacy of the legal remedy.'" *Gardner v. Safeco Ins. Co. of Am.*, No. 14-cv-02024-JCS, 2014 WL 2568895, *7 (N.D. Cal. June 6, 2014) (citations omitted). *See Salas v. Toyota Motor Sales, U.S.A., Inc*., No. cv-15-8629 FMO (Ex), 2016 WL 7486600, *13 (C.D. Cal. Sept. 27, 2016) (citing cases and dismissing UCL and unjust enrichment claims where plaintiff sought CLRA damages); *see also, e.g.*, *Robinson v. J.M. Smucker Co.*, No. 18-cv-04654-HSG, 2019 WL 2029069, *6 (N.D. Cal. May 8, 2019) (dismissing UCL claim because "an adequate remedy [wa]s available at law in that Plaintiff may seek money damages for a CLRA violation").

purchasers of a product . . . are not likely to encounter future harm of the kind that makes injunctive relief appropriate."); *Valcarcel v. Ahold U.S.A., Inc.*, No. 21-cv-07821 (JSR), 2021 WL 6106209, at *10 (S.D.N.Y. Dec. 22, 2021) (dismissing injunctive claims under *Berni*); FAC ¶¶ 54, 59, 64, 69 (alleging that if Plaintiffs had known the truth about the Product, they would not have purchased it). Plaintiffs therefore cannot plausibly allege that they will be deceived by the same Product label again.

In an attempt to avoid dismissal, Plaintiffs allege they "may be harmed again in the future because they want to purchase the Product in the future" with corrective labeling, FAC ¶ 75, but as this Court has recognized, these allegations similarly do not establish likelihood of future harm. *See Suarez*, 2019 WL 1046662, at *2, 4 (dismissing injunctive relief claims for lack of a cognizable future injury despite Plaintiff's allegations that she "continues to desire to purchase [the product] if they were accurately marketed and labeled"); *see also*, *e.g.*, *Valcarcel*, 2021 6106209, at *10 (rejecting standing notwithstanding plaintiff's contention that "she is unable to rely on the accuracy of the product's front label in the future, which causes her to avoid purchasing the product, even though she would otherwise like to do so"). Because Plaintiffs cannot demonstrate they are likely to be deceived again, their requests for injunctive relief must be dismissed.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that Plaintiffs' claims be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(6), or, in the alternative, 12(b)(1).

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